Patent Application
Docket No. BOEHM22.001APC
Serial No. 10/019,513

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Susan Ungar
Applicants	:	Peter Brossart et al.
Serial No.	:	10/019,513
Filed	:	August 6, 2002
For	:	Peptide for triggering an immune reaction against tumor cells

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PETER BROSSART, M.D., UNDER 37 C.F.R. §1.132

Sir:

I, Peter Brossart, M.D., of University of Tübingen, Department of Hematology, and Oncology, D-72076 Tübingen, Germany, hereby declare:

THAT, my *curriculum vitae* is attached hereto as Exhibit A;

THAT, I am a named inventor on the above-referenced patent application;

THAT, through my years of research, I have kept up to date on the technical literature and maintained contact with experts in the field by participating in professional meetings and seminars, and by direct personal contact. As a result, I am familiar with the general level of skill of those working in the fields of immunology and clinical transplantation, and in particular the field of graft tolerance.

THAT, I have read and understood the specification and claims of the subject application and the respective Office and Advisory Actions;

AND, being thus duly qualified, do further declare:

The enclosed publication, Brossart *et al.* (The epithelial tumor antigen MUC1 is expressed in hematological malignancies and is recognized by MUC1-specific cytotoxic T, Cancer Res. 2001 Sep 15;61(18):6846-50; Exhibit B), of which I am co-author, in particular in Figures 4 and 5 as well as in the part titled "Materials and Methods" on page 6847 thereof clearly shows that both peptides as

currently claimed having the sequences STAPPVHNV and LLLLTVLTV from MUC1 have utility in that they specifically lyse primary cancer cells.

In detail, T-cells that specifically recognize the peptides in question were not only tested against cell lines that are representative for several tumors (cf. attached table 2), and with peptide-loaded antigen-presenting cells, (dendritic cells, cf. Figure 3), but also against primary cancer cells as obtained from four different cancer patients. The patients were suffering from Acute Myeloid Leukemia (AML), a common leukemia. Figure 4 clearly shows that not only a renal cancer cell line (A498), but also said primary cancer cells from four different cancer patients are lysed. Furthermore, the cell line SK-OV-3 was used as a HLA-A2-negative control.

Figure 5 furthermore supprts the results of Figure 4 in that it is shown that T-cells are specific for the peptides as offered, and that the amount of lysis is comparable to the control lysis of peptide-loaded croft-cells. In addition, there is no cross-reactivity regarding the peptide-recognition of the T-cells.

In summary, the above references provide strong evidence for a broad utility of the peptides of the invention in different cancer types, such as leukemia and renal cell cancer.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or of any patent issuing thereon.

Further declarant sayeth naught.

Signed: _____
Peter Brossart, M.D.

Date: 02/21/06